

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION, FIELD OPERATIONS BRANCH, COMPLIANCE

CH, COMPLIANCE TEAM
4298 Elysian Fields Avenue
New Orleans, LA 70122

Telephone (504) 589-7166
Fax (504) 589-6360

December 15, 1997

WARNING LETTER NO. 98-NOL-09

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Andrew Blanchard President and Owner Triple T. Enterprises, Inc. P.O. Box 207 Chauvin, LA 70344

Dear Mr. Blanchard:

During an inspection of your firm located at 5557 Highway 56, Chauvin, Louisiana on 10/28/97 and 11/13/97, our investigator documented objectionable conditions which cause your product, peeled and deveined shrimp, to be adulterated within the meaning of Section 402(a)(3) of the Federal Food, Drug and Cosmetic Act (the Act).

During that inspection, our investigator documented that your firm repacked a lot of imported peeled and deveined shrimp into a lot of 24/1 lb. cases of peeled and deveined shrimp under your Pride and Joy label. Analysis of a sample collected from this lot by our FDA Southeast Regional Laboratory revealed the lot to contain decomposed shrimp.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Current Good Manufacturing Practice (CGMP) regulations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This may include seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the steps taken to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action can not be completed within 15 working days, state the reason for this delay and the time within which the corrections will be completed.

Your response should be directed to Richard D. Debo, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana, 70122-3896, telephone number (504) 589-7166. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the agency staff, do not hesitate to contact Mr. Debo.

Sincerely,

James E. Gamet
District Director
New Orleans District Office

/ker